Remarks/Arguments

A. Status of the Claims

No claims have been added, amended, or canceled. Therefore, claims 14-33 remain pending.

B. Applicant Elects Group I With Traverse[1]

The Examiner requests Applicant to make the following elections:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 14-28, drawn to an assay for selecting a compound that effects a sodium channel, classified variously, for example in class 536, subclass 23.1.

   II. Claims 29-33, drawn to a method of identifying a compound for treating epilepsy or other neurological disorders, classified variously, for example in class 424, subclass 94.1.

Further Restriction *(Note: This is not species selection.)*

The inventions listed as Group I are subjected to further restrictions as set forth below:

a. Applicants are further requested to select a single specific DNA sequence identified by its corresponding SEQ ID NO.

b. Applicants are further requested to select a single specific amino acid sequence identified by its corresponding SEQ ID NO.

Action at page 2.

[1] Applicant's arguments against the Restriction Requirement are based on the: (1) new policy set forth by the U.S. Patent Office; and (2) lack of an additional burden—much less a "serious burden"—to search all of the claimed sequences. Such arguments do not create an estoppel against Applicants and are not an admission that the restricted Groups are either patentably distinct or patentably indistinct from one another. This applies to all of Applicant's arguments against all of the Restrictions.

In response, Applicant elects Group I drawn to claims 14-28. Applicant also elects SEQ ID NO:65 for the nucleic acid sequence and SEQ ID NO: 67 for the amino acid sequence with traverse.

The Restriction Requirement is contrary to the U.S. Patent Office's policy in examining nucleic acid sequences. It divides the claims into several groups, thereby placing an inordinate economic burden on Applicant to obtain a reasonable scope of patent protection for the invention. The U.S. Patent Office has recognized this burden and has implemented a new policy with respect to Restriction Requirement practice for nucleic acid sequences:

> In establishing the new policy, the Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, **in most cases, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction**..

MPEP § 2434 (emphasis added); *see also id.* at § 803.04 (recognizing the economic burden "[n]evertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application...It has been determined that normally ten sequences constitutes a reasonable number for examination purposes. Accordingly, in most cases, **up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction**....") (emphasis added). Therefore, Applicant is entitled to have at least 10 additional sequences searched and requests that such a search be performed prior to issuance of the next office action.

Applicant also notes that a search of the complete claimed invention does not present a "serious burden" on the Examiner. MPEP § 803 ("[i] if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits,

even though it includes claims to independent or distinct inventions"). For instance, all of the claimed sequences relate to the same gene, *i.e.*, SCN3A, and therefore share several functional and structural features (see application). Because of these functionally and structurally similar features, there is no "serious burden" to search all of the claimed sequences. Further, even if there was a serious burden, which Applicant does not concede, Applicant is entitled to have "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." MPEP at § 803.04.

Applicant reserves all rights in the non-elected inventions, including the right to file one or more divisional applications covering the subject matter thereof.

C. Species Election Requirement

The Examiner also requests issues a Species Election Requirement and requests Applicant o elect a single species for each of the following:

> **A.) A single specific disorder.**
>
> **B.) A single specific species of a compound (or an agent).**
>
> **C.) A single specific selection of inactivation OR activation of the sodium channel.**
>
> **D.) A single specific mammalian species from which the sodium channel sequence is derived.**
>
> **E.) A single specific selection of a cell-free system OR a whole cell system.**

Action at page 4.

In response, Applicant elects the following species with traverse:

A. Idiopathic Generalized Epilepsy (IGE);
B. Chemical Compound (or agent) (see specification at page 20, lines 22-24);
C. Inactivation;
D. Human SCN3A; and
E. Cell-Free System

Applicant believes that claims 14-23, 25, 27, and 28 (from elected Group 1) read on the elected invention.

While Applicant may understand that for initiating searching, the species election of one disorder ("A"), and perhaps one mammalian species ("D") and whether the assay involves inactivation or activation ("C") might be helpful, the same cannot be comprehended for the type of compound ("B") or the type of assay *per se* ("E"). For example, Applicant fails to see how the type of library of compounds could have an impact on the patentability of an assay set-up to screen candidate compounds of different origin, structure, size, *etc.* Applicant believes that the compounds, whether the assay is cell-based, whether a human or other mammalian sequence is used, which way the modulation of diseased function occurs and the associated disease, should not be considered essential elements to assess whether the claimed assays to identify modulators of sodium channel activity of SCN3A are patentable. Accordingly, it is requested that the species be rejoined immediately.

Applicant agrees with the Examiner that "[u]pone the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141." Action at page 5.

D. Conclusion

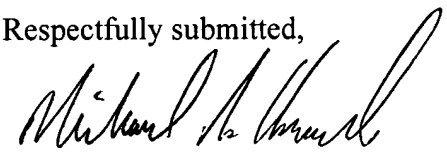
Applicant believes that this is a full and complete response to the Restriction Requirement mailed June 20, 2006. Applicant requests that the Restriction Requirement be withdrawn and that all claims be examined for the their full scope.

Petition for a Two-Month Extension of Time

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for a two-month extension of time to and including September 20, 2006, in which to respond to the Restriction Requirement mailed June 20, 2006. Pursuant to 37 C.F.R. § 1.17, a check in the amount of $225.00 is enclosed, which is the process fee for a two-month extension of time for a small entity status. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/GOUD:023USD1.

Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-3020.

Respectfully submitted,



Michael R. Krawzsenek
Reg. No. 51,898
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3020
(512) 536-4598 (facsimile)

Date: September 20, 2006